IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Houston Division

NATURAL ALTERNATIVES INTERNATIONAL, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 11-4511
WOODBOLT DISTRIBUTION, LLC, *et al.*,	)	
Defendants.	)	

REPLY IN SUPPORT OF PLAINTIFF'S CROSS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT BY WOODBOLT AND THAT THE PATENTS-IN-SUIT ARE NOT INVALID

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INTRODUCTION

Plaintiff Natural Alternatives International, Inc.'s ("NAI") cross motion for summary judgment of infringement (Dkt. No. 63) by defendant Woodbolt Distribution, LLC ("Woodbolt") and that the patents-in-suit are not invalid should be granted. Many patent infringers, when faced with the fact that they clearly infringed a patent, resort to last-ditch efforts to try to invalidate that patent, but those efforts fail here. Woodbolt did not raise a non-infringement defense as ordered by this Court and failed to prove by clear and convincing evidence that NAI's U.S. Patent Nos. 8,067,381 ("the '381 patent") and 8,129,422 ("the '422 patent") are invalid pursuant to 35 U.S.C. §§ 102 and 103.[1] Woodbolt's C4 Extreme, M5 Extreme, and N-Zero Extreme products (the "Accused Products") infringe valid claims of the patents-in-suit and the Court should grant summary judgment accordingly.

Woodbolt falsely accuses NAI of trying to use two different claim constructions for invalidity and infringement. It is Woodbolt that is trying to have it both ways. For purposes of its own summary judgment motion of invalidity, Woodbolt agrees that "human dietary supplement" is a claim limitation as NAI defined it in the prosecution history. In responding to NAI's cross motion, however, Woodbolt says it is not bound by that limitation, even though the basis for rebutting NAI's cross motion lies in its own summary judgment motion. Clearly, the claim construction must be the same for both invalidity and infringement.

[1] Woodbolt's response is even devoid of any evidence that the dependent claims of the patents-in-suit, which require additional elements such as creatine, L-histidine, carbohydrates and insulin, or insulin stimulating agents, are invalid.

ARGUMENT

I. NAI'S CROSS MOTION FOR SUMMARY JUDGMENT OF VALIDITY SHOULD BE GRANTED.

A. The Court Should Adopt NAI's Claim Constructions.

1. "Human Dietary Supplement" As Used In The Claims Of The '381 Patent Should Be Construed As A Limitation In Conformity With The Intrinsic Evidence.

In its motion, Woodbolt agreed that the term "human dietary supplement" is a claim limitation that should be given the meaning expressly defined by NAI in the prosecution history. (Dkt. No. 53 at 7). In its reply and opposition, Woodbolt backpedals and asks the Court to give a different construction when considering NAI' cross motion. But it cannot be disputed that the term "human dietary supplement" is a claim limitation and that the term means, as detailed in NAI's brief at 6-11:

> an addition to the human diet in a pill, capsule, tablet, powder, or liquid form for effectively increasing the function of tissues when consumed, where the addition is not a natural or conventional food, meat or food flavoring, and is not a pharmaceutical product.

(Dkt. No. 63 ("NAI Br.") at 7, quoting Ex. 4 at 5). Prior art that fails to disclose a human dietary supplement as so defined is irrelevant. Woodbolt's argument that the term is not a limitation and that the Court should simply ignore the ordinary meaning of the term and the prosecution history is meritless.[2]

NAI's brief detailed that the prosecution history, in particular the First Preliminary Amendment, expressly defined the meaning of "human dietary supplement":

[2] Moreover, it begs a fundamental question: since Woodbolt stipulated to the meaning of "human dietary supplement" as defined by NAI to support its motion for summary judgment of invalidity, and its entire basis as to why it does not infringe the patents-in-suit and that they are invalid is based on the same argument, why would it seek a second claim construction for the same propositions?

> By human dietary supplements the applicants mean an addition to the human diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food, and which effectively increases the function of tissues when consumed. . . . To be clear, the term "human dietary supplement", as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example.

(NAI Br. at 7, quoting Ex. 4 at 5). This is a definite and unmistakable disavowal of claim scope set forth with clarity and deliberateness. *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 994-95 (Fed. Cir. 2003) (a disavowal of claim scope during prosecution limits the claim); *Pall Corp. v. PTI Techs. Inc.*, 259 F.3d 1383, 1392 (Fed. Cir. 2001) ("the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). Thus, even if the claims had not called out the terms in dispute such as "effective," they would still be part of the claimed subject matter.[3] This definition thus limited the meaning of the claim term, and after NAI filed the Preliminary Amendment, the Examiner allowed the claims to issue. (NAI Br. Ex. 8). Limiting language contained in the prosecution history, including a Preliminary Amendment such as this, are to be given effect. *PTI Techs. Inc.*, 259 F.3d at 1392. Woodbolt erroneously contends that a functional limitation adds no patentable weight because the '381 patent is to composition claims.[4] Moreover, NAI has

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[3] To achieve this limitation, the disclaimer must be made with "reasonable clarity and deliberateness." *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294 (Fed. Cir. 2000). Here, there is no doubt the inventors were disclaiming what Woodbolt alleges is part of the claims.

[4] The MANUAL OF PATENT EXAMINING PROCEDURE § 2173.05(g) directly contradicts Woodbolt with respect to functional limitations: "**A functional limitation is an attempt to define something by what it does, rather than by what it is** (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. **Functional language does not, in and of itself, render a claim improper**…. A functional limitation **must be evaluated and considered, just like any other limitation** of the claim, for what **it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used**. A functional limitation is often used in association with an element, ingredient, or step of a process **to define a particular capability or**

previously shown that the prosecution history of the '381 patent was not before Judge Sleet. It is not a coincidence that NAI submitted Judge Sleet's claim construction order to the PTO to expressly distinguish the '381 patent application from the earlier patents. Consequently, Judge Sleet's order is entirely irrelevant here. (NAI Br. at 7, 20-21).

The term "human dietary supplement" must also be construed to exclude "meat or food flavorings" and pharmaceutical products. Again, the First Preliminary Amendment expressly disclaimed "beef, pork, chicken, meat extract supplements and predigested meat/protein supplements" or "other naturally occurring compositions." (NAI Br. at 7 & n.3 & Ex. 4 at 6). A "pharmaceutical" does not fall within the definition set forth in the Preliminary Amendment and the specification also distinguished dietary supplements from pharmaceutical drugs. (NAI Br. at 8). Finally, as a matter of law, a dietary supplement is not a pharmaceutical drug. 21 U.S.C. § 321(ff)(3). These limitations should not be read out of the construction of the "human dietary supplement" term in the patent claims. NAI's proposed construction, agreed to by Woodbolt in its opening brief, should be adopted.

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purpose that is served by the recited element, ingredient or step." (Emphasis added.) *See also Geneva Pharms., Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373, 1383-84 (Fed. Cir. 2003) (affirming the district court; finding patentable weight for functional limitations in the composition of matter claims, and stating that "'effective amount' is a common and generally acceptable claim" in composition claims); *Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 313 F. Supp. 2d 405, 410-11 (D. Del. 2004) (finding patentable weight for functional limitations in the composition of matter claims such as "effective amount" and "enhancing amount" *and* that such functional terms removed any prior art that had small amounts that did not exhibit the functional limitation).

2. The Relevant Claims Of The '422 Patent Must Be Construed To Give Effect To All Of The Claim Terms.

Woodbolt's response also fails to resurrect its erroneous construction of Claim 12 of the '422 patent. In an effort to "simplify" the construction for its own benefit, Woodbolt intentionally dilutes the meaning of Claim 12, stripping it of essential claim terms. Claim 12 of the '422 patent should be construed to mean:

> A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse) as a dietary supplement a large enough amount of the amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased. [NAI Br. at 13]

NAI's inventors were the first to teach that repeated administration of beta-alanine in high amounts over many days can lead to an increase in the levels of dipeptides in the **muscles**. Woodbolt points to places in the specification that discuss levels of beta-alanine in the **blood** found after administering beta-alanine one or three times in a single day. (Dkt. No. 66 at 10). That is, of course, irrelevant because the claims of the '422 patent are drawn to increasing beta-alanylhistidine synthesis in the **muscle**. Woodbolt has not rebutted NAI's scientific evidence that "around 3.2 grams of beta-alanine supplementation, [administered] daily, can likely impart the desired benefits" of increased levels of dipeptides in human muscles and delaying the onset of muscular fatigue in humans that is "*only achieved after at least three to four weeks of continuous usage*." (NAI Br. Ex. 9 at 5, emphasis added); *see also* Ex. 10 at 18) ("Beta-Alanine takes 1-2 weeks of **continued use** for it **to start** increasing performance gains." (Emphasis added).

These scientific facts refute Woodbolt's unsubstantiated attorney argument that the '422 patent recites "inherent" results. (NAI Br. at 13-14). As NAI explained, the references relied on by Woodbolt in support of its oversimplification are further unavailing, as they offer no support

for Woodbolt's assertion that the '422 patent's "simplified" claim broadly covers providing beta-alanine as a single amino acid to a subject. (*Id*. at 14-17). Woodbolt simplified to its detriment, choosing not to construe all terms of Claim 12. (*Id.* at 18-20).

The Hama rat study relied on by Woodbolt does not teach that the administration of single amino acid beta-alanine in a sufficient dosage over a long period of time will delay the onset of muscular fatigue – a requirement of the claims – and Woodbolt cannot argue to the contrary. Indeed, Hama taught away from the claimed invention. Hama reported that large doses of carnosine lead to a **reduction** of carnosine in the rat's calf muscle and harm to the ability to buffer. (NAI Br. at 17; Ex. 14 at 152-53, Figs. 5-6, dosage H). Hama also did no test of muscular fatigue and there was no finding of any effective increase. Woodbolt asks this Court to risk error by finding facts without any evidentiary support in the record. "Hearsay, conclusory allegations, unsubstantiated assertions, and unsupported speculation are not competent summary judgment evidence." *Tesco Corp. v. Weatherford Int'l Inc.*, 722 F. Supp. 2d 755, 769 (S.D. Tex. 2010). Hama simply does not support inherency.

Woodbolt also ignores that Claim 19 of the '422 patent is directed to human subjects. Woodbolt admits (at 12) that Hama force fed rats through a stomach tube more than **40 times** the dosage equivalent in the patents-in-suit. (NAI Br. at 16; Ex. 14 at 150 Fig. 2). This extraordinarily high dose would cause humans to experience extremely painful paraesthesia, an abnormal sensation of skin burning or prickling. (*Id.*; Ex. 10 at 17). Hama does not teach the effects of a normal dose of beta-alanine.

B. Woodbolt's Cited References Do Not Anticipate The '381 Patent Claims.

None of Woodbolt's references anticipate the claims of the '381 patent under 35 U.S.C. § 102. Woodbolt reargues that Asatoor and Gardner anticipate because they both describe a test in which the subject was given a dosage that was "within the recommended range of dosages

described in the '381 patent." (Dkt. No. 66 at 8). However, to be an anticipating reference under § 102, all of the elements of the claim arranged as in the claim must be disclosed in a single prior art reference. (NAI Br. at 21-22, citing case law). As discussed above, Claim 1 of the '381 patent is drawn to a human dietary supplement that, *inter alia*, "*effectively* increases the function of tissues when consumed." Claim 13 is further limited to a human dietary supplement *effective* in delaying the onset of fatigue in a human. Simply put, disclosure of mere dosage in Asatoor and Gardner does not contain all of the elements of the claim sufficient to satisfy § 102 by clear and convincing evidence. There is no disclosure that a single dosage of beta-alanine will effectively increase the function of tissues or delay the onset of fatigue. Woodbolt concedes that the Asatoor test involved giving five subjects a single dose at an interval of two weeks, and Gardner involved using a single dose. (Dkt. No. 66 at 8). These references do not anticipate.[5]

Nor does the DeLacharriere wrinkle cream patent anticipate, as Woodbolt claims (at 8-9). A skin cream is not a "human dietary supplement." The First Preliminary Amendment submitted by NAI clearly limited Claim 1 to be, *inter alia*, "an addition to the human diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food and which effectively increases the function of tissues when consumed" (NAI Br. Ex. 4 at 5). A cream is applied to the skin, it is not consumed. It is certainly not an addition to the human diet. Woodbolt cannot rely on DeLacharriere to defeat NAI's cross motion for summary judgment.

The Pittet and Wilson references disclose meat or food flavorings and European Patent 0280593 ("EP '593") discloses a cancer therapy pharmaceutical. (Dkt. No. 66 at 7 n.8). As set forth above, NAI disclaimed such food flavorings and a human dietary supplement does not

[5] Woodbolt suggests that Asatoor and Gardener give the multiple doses necessary. This is unavailing since both references demonstrate that intervals between doses were separated by a

include pharmaceuticals. These references do not disclose dietary supplements that effectively increase the function of tissues when consumed. Thus, these three references are not invalidating prior art. NAI's cross motion on this patent should be granted.

C. The Cited References Do Not Anticipate Claims Of The '422 Patent.

Woodbolt implicitly asks this Court to find scientific facts that are unsupported by record evidence and that are simply not true.[6] Woodbolt argues (at 14-15) that Asatoor, Gardner and EP '593 describe beta-alanine dosages within the ranges described in the '422 patent and describe multiple dosages. As discussed above, disclosure of a dosage is not sufficient. Additionally, the properly construed claims require multiple dosages "over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased." None of the dosages of Asatoor, Gardner or EP '593 were given for a sufficiently long period to achieve the claimed invention. As Woodbolt concedes, the Asatoor test involved giving five subjects a single dose two weeks apart, and Gardner involved using a single dose. (Dkt. No. 66 at 8; NAI Br. Ex. 11 at 250-51, Ex. 12 at 413). EP '593 does not state a beta-alanine dosage, only a suggested dosage for amino acids that may include beta-alanine to be given to a cancer patient.; it does not state how long the beta-alanine is given. (NAI Br. Ex. 20). NAI's undisputed scientific references require a longer period of dosing – increased levels of dipeptides in human muscles and delaying the onset of muscular fatigue in humans is "only achieved after at least three to four weeks of **continuous usage**." (NAI Br. at 14, Ex. 9 at 5, emphasis added); *see also* Ex. 10 at 18 ("Beta-Alanine takes 1-2

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week or more, such that beta-alanine blood levels could not possibly be affected by earlier consumptions.

[6] Woodbolt's theory requires this Court to find that a single exposure to beta-alanine is effective to increase muscle function, when the scientific evidence and patents at issue show continuous doses over weeks must be used to obtain this result.

weeks of **continued use** for it to start increasing performance gains." Emphasis added)). Woodbolt's three references are not anticipating.

Hama does not anticipate the '422 patent either. As discussed above, Hama does not disclose taking multiple dosages over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle. Woodbolt again completely ignores Claim 19 of the '422 patent, which is limited to a human subject. The rat study says nothing about a method of use for a human and it prescribes a dosage level more than 40 times higher than set forth in the patent, resulting in a painful paraesthesia effect that would result in a person not being able to take, much less tolerate, the dose disclosed.

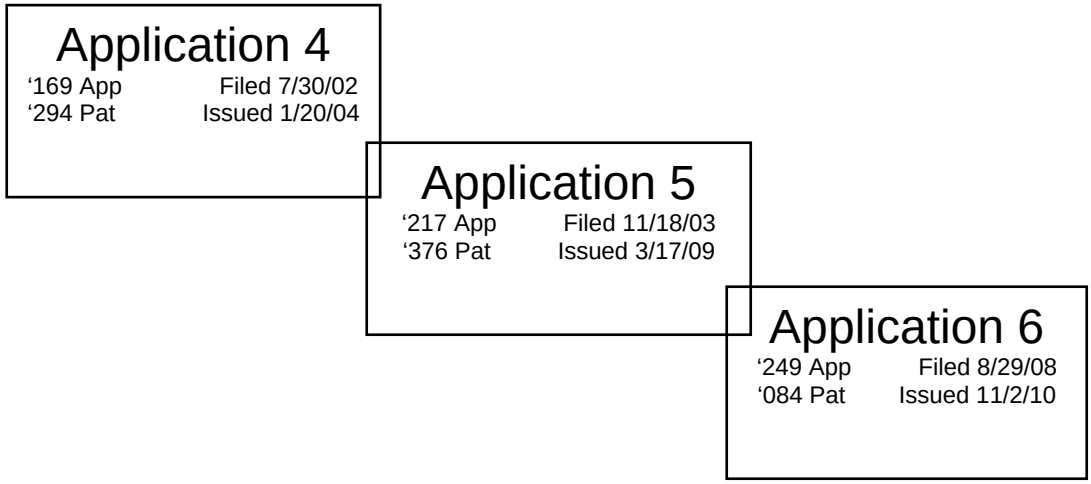
D. Woodbolt's Anticipation Argument Does Not Address The Dependent Claims Of The Patents.

Woodbolt's entire case of anticipation also fails to address the dependent claims of the patents-in-suit. These dependent claims include Claim 13 of the '381 patent (which explicitly and literally incorporate the "effective" amount requirement) and Claim 19 of the '422 (which not only literally requires the "effective amount" but also is directed to use in a human). Woodbolt also fails to address those other dependent claims that require the dietary supplement to combine beta-alanine with other things, such as creatine, *e.g.*, Claims 8-9 in the '381 patent and Claim 14 in the '422 patent. Other dependent claims include combining beta-alanine and L-histidine, carbohydrates and insulin, or insulin stimulating agents, *e.g.*, Claims 3, 5, 6 and 7 of the '381 patent and Claim 13 of the '422 patent. Each limitation in a claim – even dependent claims – must be addressed to show inherent anticipation. Even if Woodbolt were able to show prior art ingestion of beta-, Woodbolt must still show where the alleged prior art discloses using beta-alanine as a dietary supplement together with the other compositions required by the claims.

Woodbolt does not address these issues and there is no evidentiary support to prove anticipation by clear and convincing evidence. Those dependent claims should be found to be not invalid.

E. There is No "Break" In The Priority Chain of the Patents-In-Suit And No Anticipation by NAI's Own Patent.

Woodbolt continues to rely on its faulty arguments, failing to present any additional evidence or any legal authority, that NAI's own patent (U.S. Patent No. 5,965,596) invalidates the patents-in-suit because there was an alleged "break" in priority. As NAI explained in detail, the patents-in-suit satisfied all three prerequisites of 35 U.S.C. § 120 to receive the benefit of the priority of their earlier filed applications. (NAI Br. at 30-36). Woodbolt cannot deny this. Instead, Woodbolt maintains its unsupported argument that a subsequent amendment to an intermediate application somehow retroactively nullifies a statutorily-conforming claim to priority. It does not. The following diagram shows that Application 4 was copending with Application 5, which in turn was copending with Application 6:



The following propositions are undisputable:

(1) Woodbolt admits that Applications 1-4 satisfied §120;

(2) Application 5 was filed on November 18, 2003, claiming priority to Application 4 before Application 4 issued, satisfying §120;

(3) Application 6 was filed on August 29, 2008, claiming priority to Application 5 before Application 5 issued, satisfying §120;

(4) Therefore, Application 6 has priority to Application 1.

The relevant date for §120 compliance for Application 6 was the date it was filed, August 29, 2008. Any subsequent amendment to a different specific application does not affect a previously filed claim to priority. Woodbolt's argument on this issue invites error. NAI's priority claims are correct as a matter of law.

F. Woodbolt's Obviousness Argument Is Specious.

The '381 patent is not obvious.[7] As NAI set forth, Woodbolt's reliance on combining the Setra and Asatoor references for its obviousness argument necessarily fails. (NAI Br. at 27-29). A person of ordinary skill in the art would *not* have combined these two references, to ascertain or perform the '381 patent's invention.[8] "Secondary considerations" of non-obviousness further belie Woodbolt's argument. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007). Industry recognition and awards to the named inventor on the patents-in-suit, in addition to commercial success of the patented invention, further prove non-obviousness. (NAI Br. at 4, 30). Woodbolt asserts (at 16) that NAI proffered as evidence of commercial success a license taken by a company to avoid litigation. However, NAI proffered no such evidence. Instead, NAI directed the Court's attention to the revenue received from its licensed CarnoSyn® distributor, which was not licensed as the result of litigation. (NAI Br. at 4).[9] Accordingly, Woodbolt's motion for

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[7] Woodbolt failed to raise obviousness arguments as to the '422 patent, and therefore concedes that the '422 patent is non-obvious.

[8] Woodbolt did not dispute that Setra teaches use of a dipeptide while the patents claim use of beta-alanine as a single amino acid. Hama, Woodbolt's own reference, indicates that feeding carnosine destroys the buffering system the patents-in-suit protect. (NAI Br. at 17).

[9] Since 2010, NAI has also exclusively licensed the patents-in-suit for certain fields of use to Abbott Laboratories and Nestle. (Dkt. No. 11 ¶ 15). Neither were in the context of resolving litigation.

summary judgment of invalidity should be denied and NAI's cross motion for summary judgment should be granted.

II. NAI'S CROSS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT SHOULD BE GRANTED.

There are no genuine issues of disputed material fact that Woodbolt's Accused Products infringe the patents-in-suit, thus NAI's cross motion for summary judgment should be granted. Woodbolt failed to raise any non-infringement position, despite the Court affording it multiple opportunities to do so, including being ordered to file a stipulation (which presented no grounds supporting non-infringement or a summary judgment motion of non-infringement). As noted above, Woodbolt argues that for purposes of its summary judgment motion of invalidity, "human dietary supplement" is a claim limitation. In opposing NAI's cross motion of validity and infringement, Woodbolt contends that the term is not a limitation. Under either scenario, Woodbolt's Accused Products fall within the scope of one or more claims of the patents-in-suit and a finding of infringement should be made. The same construction must be used for invalidity and infringement. Under the properly construed claims, Woodbolt infringes.

A. Woodbolt Infringes The '381 Patent.

Properly construed, Claim 1 of the '381 patent means:

> A human dietary supplement – meaning an addition to the human diet in a pill, capsule, tablet, powder, or liquid form for effectively increasing the function of tissues when consumed, where the addition is not a natural or conventional food, meat or food flavoring, and is not a pharmaceutical product – comprising beta-alanine as a single amino acid, unbonded to a different amino acid.

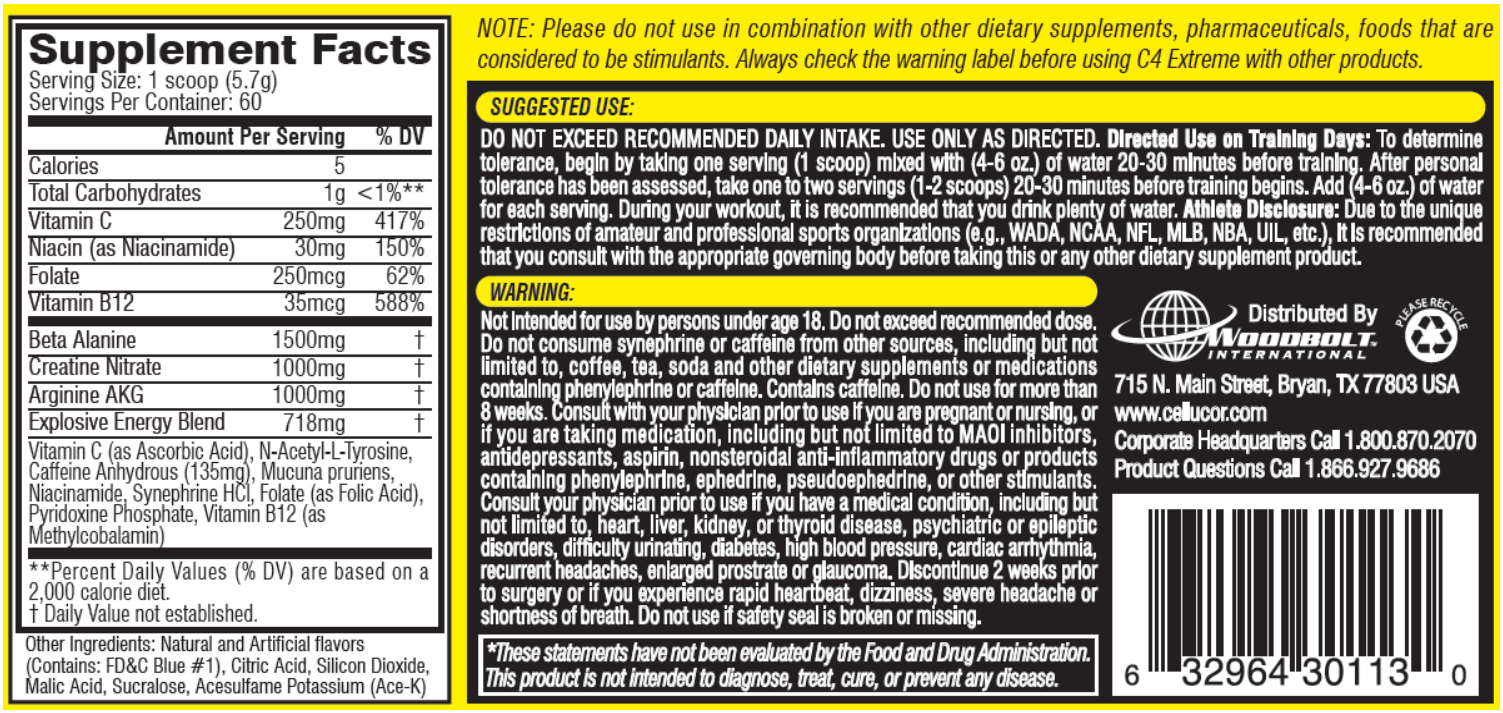
Claim 13 of that patent depends from Claim 1 and is further limited to "wherein the human dietary supplement is effective in delaying the onset of fatigue in a human."

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention within the United States or imports into the United States any patented invention during the term

of the patent therefore, infringes the patent." 28 U.S.C. § 271(a). In determining infringement, the court compares properly-construed claims to the accused product to determine "whether the accused device is within the scope of the claim." *Charles Greiner & Co. v. Mari-Med Mfg., Inc.*, 962 F.2d 1031, 1034 (Fed. Cir. 1992); *MGM Well Servs., Inc. v. Mega Lift Sys., LLC*, 505 F. Supp. 2d 359, 366 (S.D. Tex. 2007), *aff'd without op*., 2008 U.S. App. Lexis 3446 (Fed. Cir. Feb. 19, 2008). A patentee must establish infringement by a preponderance of the evidence. *See, e.g., Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 819 (Fed. Cir. 1992).

Woodbolt does not argue that the Accused Products do not contain beta-alanine as a single amino acid, unbonded to a different amino acid. As such, the Court should find that this element is met. Nor does Woodbolt contest – because it cannot – that the Accused Products are not in the form of a powder, which the preliminary amendments to the patents-in-suit specifically called out.[10] (Dkt. No. 53 at 7, quoting Ex. 4 at 5). Woodbolt's Accused Products – C4 Extreme, M5 Extreme and N0 Extreme – are undoubtedly a "human dietary supplement." For example, its label states C4 Extreme is a "Dietary Supplement":

[10] The Accused Products are in solid form and thus infringe Claim 11 of the patent.



Supplement Facts
Serving Size: 1 scoop (5.7g)
Servings Per Container: 60

	Amount Per Serving	% DV
Calories	5	
Total Carbohydrates	1g	<1%**
Vitamin C	250mg	417%
Niacin (as Niacinamide)	30mg	150%
Folate	250mcg	62%
Vitamin B12	35mcg	588%
Beta Alanine	1500mg	†
Creatine Nitrate	1000mg	†
Arginine AKG	1000mg	†
Explosive Energy Blend	718mg	†

Vitamin C (as Ascorbic Acid), N-Acetyl-L-Tyrosine, Caffeine Anhydrous (135mg), Mucuna pruriens, Niacinamide, Synephrine HCl, Folate (as Folic Acid), Pyridoxine Phosphate, Vitamin B12 (as Methylcobalamin)

**Percent Daily Values (% DV) are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Natural and Artificial flavors (Contains: FD&C Blue #1), Citric Acid, Silicon Dioxide, Malic Acid, Sucralose, Acesulfame Potassium (Ace-K)

NOTE: Please do not use in combination with other dietary supplements, pharmaceuticals, foods that are considered to be stimulants. Always check the warning label before using C4 Extreme with other products.

SUGGESTED USE:

DO NOT EXCEED RECOMMENDED DAILY INTAKE. USE ONLY AS DIRECTED. **Directed Use on Training Days:** To determine tolerance, begin by taking one serving (1 scoop) mixed with (4-6 oz.) of water 20-30 minutes before training. After personal tolerance has been assessed, take one to two servings (1-2 scoops) 20-30 minutes before training begins. Add (4-6 oz.) of water for each serving. During your workout, it is recommended that you drink plenty of water. **Athlete Disclosure:** Due to the unique restrictions of amateur and professional sports organizations (e.g., WADA, NCAA, NFL, MLB, NBA, UIL, etc.), it is recommended that you consult with the appropriate governing body before taking this or any other dietary supplement product.

WARNING:

Not intended for use by persons under age 18. Do not exceed recommended dose. Do not consume synephrine or caffeine from other sources, including but not limited to, coffee, tea, soda and other dietary supplements or medications containing phenylephrine or caffeine. Contains caffeine. Do not use for more than 8 weeks. Consult with your physician prior to use if you are pregnant or nursing, or if you are taking medication, including but not limited to MAOI inhibitors, antidepressants, aspirin, nonsteroidal anti-inflammatory drugs or products containing phenylephrine, ephedrine, pseudoephedrine, or other stimulants. Consult your physician prior to use if you have a medical condition, including but not limited to, heart, liver, kidney, or thyroid disease, psychiatric or epileptic disorders, difficulty urinating, diabetes, high blood pressure, cardiac arrhythmia, recurrent headaches, enlarged prostrate or glaucoma. Discontinue 2 weeks prior to surgery or if you experience rapid heartbeat, dizziness, severe headache or shortness of breath. Do not use if safety seal is broken or missing.

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.*

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(Ex. A; *see also* Exs. B, C). Further, Woodbolt has judicially admitted that its C4 is a dietary supplement as a matter of law. (Ex. F).

Woodbolt also represents to the public that its product is effective to increase the functioning of tissues and to delay the onset of fatigue:

> **C4 Extreme is powdered energy.** You will have more energy than ever imagined possible from a supplement. You will get that extra rep, complete that last set—detonating any previous strength, endurance, and physique personal bests.
>
> Beta Alanine is an effective fatigue arrester — it acts as a buffer, preventing lactic acid accumulation in skeletal muscle (which occurs during exercise) allowing the body to perform better, longer."

(Dkt. No. 10 Ex. 8, emphasis in original; *see also* Ex. D). The exhibit Woodbolt attached to its Stipulation for C4 and the other two Accused Products erases any doubt:

> Beta Alanine is a naturally occurring amino acid. Beta Alanine produces higher intramuscular carnosine levels which amplifies energy levels, supports muscular endurance, and improves performance. Beta Alanine is an effective fatigue arrester— [sic] it

> acts as a buffer, preventing lactic acid accumulation in skeletal muscle (which occurs during exercise) allowing the body to perform better, longer.

(Dkt. No. 52).

Further, Woodbolt's labels for C4 provide a dosage – 1 scoop (5.7 grams), which contains 1,500 milligrams of beta-alanine. Under "Suggested Uses" the label tells its customers: "DO NOT EXCEED RECOMMENDED DAILY INTAKE" and "Do not use for more than 8 weeks." (Ex. A). The Accused Product may be taken at the recommended dosage everyday for eight weeks as the label on the container states there are 60 servings in the container. (*Id.*).

Thus, each claim limitation for Claims 1, 11 and 13 is met and the Accused Products infringe those claims.

B. Woodbolt Also Indirectly Infringes Claims Of The '422 Patent.

Woodbolt also indirectly infringes claims of the '422 patent by inducing infringement by its customers who use its Accused Products. Indirect infringement by the defendant requires a showing of direct infringement by a third party. *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006).

As NAI previously argued, the properly construed Claim 12 of the '422 means:

> A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse) as a dietary supplement a large enough amount of the amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the muscle is increased.

Claim 19 of the '422 patent covers human subjects. For the same reasons set forth above, the Accused Products infringe Claims 12 and 19.

It cannot be disputed that Woodbolt's customers are directly infringing the '422 patent by using the Accused Products. Woodbolt's barebones Stipulation provides few facts relating to how its customers use the product. However, it does admit that:

> Woodbolt's C4 Extreme is used by athletes such as bodybuilders as a pre-workout intensifier.
>
> Woodbolt's M5 Extreme is used by athletes such as bodybuilders as pre-workout muscle building supplement.
>
> Woodbolt's NO Extreme is used by athletes such as bodybuilders as pre-workout supplement to enhance muscle definition and tone, increase endurance, maximize athletic performance and expedite recovery.

(Dkt. No. 52). Further, Woodbolt's social media outlets confirm that its customers are using the Accused Products for the claimed method. (Dkt. No. 14 Exs. 23, 31; Ex. E). Numerous customers of the Accused Products have made and posted videos on YouTube stating that they took the products as directed on the product labels, using one or two scoops over a prolonged period of time. (Declaration of Richard J. Oparil ¶ 9, attached hereto).

Woodbolt's actions induced infringing acts by its customers. *See* 35 U.S.C. § 271(b); *DSU Med. Corp.*, 471 F.3d at 1304. Woodbolt's sales, advertising, and marketing of the Accused Products induce its customers to infringe the '422 patent. The clear and unambiguous instructions and representations presented in Woodbolt's advertisements and marketing materials direct Woodbolt's customers to take steps that infringe the '422 patent. As discussed above, the Accused Products may be taken at the recommended dosage everyday for eight weeks. (Exs. A, C, E; *see also* Dkt. No. 14 Exs. 8-13). Further, Woodbolt knew or should have known such actions would induce actual infringement. *See* 35 U.S.C. § 271(b); *DSU Med. Corp.*, 471 F.3d at 1304. NAI publicly announced the issuance of the patent on March 21, 2012 and the subject of news stories on March 21 and 22. NAI further maintains a virtual marking website. (Dkt. Nos. 14

Exs. 2-7, 20). Woodbolt actively and knowingly induced its customers to infringe the '422 patent.

Woodbolt also contributed to its customers' infringement of the '422 patent. The definition of contributory infringement is set forth in 35 U.S.C. § 271(c):

> Whoever offers to sell or sells . . . a component of a patented machine, manufacture, combination, composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, shall be liable as a contributory infringer.

Woodbolt knows that the Accused Products were especially designed for use in a way that would infringe the '422 patent and there is no substantial non-infringing use for these products. As highlighted in Woodbolt's own advertising and marketing materials, the reason customers would purchase the Accused products is to practice the methods claimed in the '422 patent. Woodbolt's sales, advertising, and marketing of the Accused Products to its customers constitute contributory infringement.

Woodbolt tries to delay a finding of infringement by suggesting their products do not satisfy the "effective" limitations that are part of the patents-in-suit and that they just practice the prior art. That belies the facts: they claim their products are effective for the same use as that disclosed and claimed in the patents, as disclosed on their product labels, advertising and the Stipulation it filed with the Court; they also tell their customers to take the material over time, and they cannot now show facts to the contrary. Accordingly, NAI's cross motion for summary judgment of infringement of Claims 12 and 19 of the '422 patent should be granted.

III. THE PTO'S PRELIMINARY ACTION IN AN *INTER PARTES* REEXAMINATION PROCEEDING IS NOT BINDING ON THIS COURT.

In another transparent attempt to argue this Court is mandated to adopt Woodbolt's faulty arguments, it claims the Court is bound by the PTO's preliminary grant of request for reexamination and First Office Action rejecting claims. Woodbolt continues to knowingly exaggerate the significance of these events in its response, which are routine and irrelevant to the current motions. (NAI Br. at 36-38). While Woodbolt claims that the Examiners have stated that Woodbolt has demonstrated a likelihood that the requester will prevail, that is not the standard for deciding summary judgment. Woodbolt's claim that the reexamination will be completed quickly is sheer fantasy. This Court emphatically denied Woodbolt's suggestion that this case be stayed pending the PTO. According to the PTO's recent statistics, the average pendency for all *inter partes* is about three years, and approximately 70% of reexaminations are in litigation. (NAI Br. Ex. 23). NAI plans to vigorously respond to Woodbolt's reexamination submissions. It will take much longer than Woodbolt's unsupported assurance to this Court. There is no deadline for the PTO to act. Reexamination is a complex process. (Ex. G). In the meantime, this Court will have long since decided the case. *Tesco Corp.*, 722 F. Supp. 2d at 761 ("Federal patent law requires an inter partes re-examination to terminate when a final decision upholding or invalidating the same patent is entered in a related civil action. 35 U.S.C. § 317(b)."). "'The principle that justice delayed is justice denied applies with full force to the patent process.'" *ESN, LLC v. Cisco Sys., Inc.*, C.A. No. 08-20, Order at 5-6 (E.D. Tex., Nov. 20, 2008) (quoting Senate testimony) (Ex. H). It is certainly disingenuous for Woodbolt to argue that the PTO will quickly consider the reexamination, when it waited until this case was pending for seven months before requesting reexamination.

CONCLUSION

For the reasons stated in NAI's brief and this reply, the Court should grant NAI's cross motion.

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CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2012, a copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

/s/ Richard J. Oparil
Richard J. Oparil